REMARKS

Claims 1 - 21 are pending the application; Claims 1 - 21 stand rejected. By this Amendment Claims 8-9 have been canceled and Claims 1, 2, 4, 11 and 18-19 have been amended. These amendments add no new matter to the application.

Claims 1 - 21 stand rejected under 35 USC §112 as allegedly not enabled by the specification; Applicant respectfully traverses these rejections. The Examiner states that the specification does not provide reasonable enablement for claims directed to plant matter of the family Theacese, or plant matter of the genus Camellia, or plant matter of the species sinensis, or green tea, green tea leaves, or green tea derivatives, or catechins, bioflavonoids, flavanols, flavandiols, tannins or their derivatives. On the contrary, Applicant submits that the specification does provide reasonable enablement for claims directed to plant matter of the family Theacese, plant matter of the genus Camellia, plant matter of the species sinensis, and green tea, green tea leaves, or green tea derivatives, as well as for claims directed to catechins, bioflavonoids, flavanols, flavandiols, tannins and their derivatives.

For instance, the Examiner's attention is respectfully directed to the following pages: page 3 lines 33-34, page 4 lines 25-32, page 9 lines 3-7 and page 14 lines 13-17 for support for claims directed to plant matter of the family Theacese, or plant matter of the genus Camellia, or plant matter of the species sinensis; to page 4 lines 21-24, page 27 lines 2-5 and page 28 lines 1-5 for support for claims directed to green tea, green tea leaves, or green tea derivatives; and to page 5 line 9 to page 6 line 2, page 11 lines 7-10, page 13 lines 16-33, page 14 lines 3-12, page 16 lines 9-27 and pages 26-27 in toto for support for claims directed to catechins, bioflavonoids, flavanols, flavandiols, tannins or their derivatives.

It is also respectfully submitted that the Examiner misconstrues the purpose and import of the working examples provided in the specification. Firstly, Applicant is aware of no legal requirement to provide such examples at all; and when they are provided they are never intended

as exclusive of otherwise enabled embodiments. Applicant expressly states at page 29, lines 18-19, that the "invention is not limited to the examples." There is no authority for the Examiner's reliance on a supposed lack of working examples as to how any of the other claimed embodiments may be employed in the claimed methods. The method claims at issue all clearly state their mode of employment, and no experimentation at all is required to practice the invention as variously claimed, it being well accepted by those skilled in the art that determination of appropriate therapeutically effective amounts of claimed compositions is not considered to be experimentation. This is particularly true when, as is presented in this case, the efficacy of the disclosed alternate embodiments is so great in general as to render practically any amount of any of the disclosed embodiments at least minimally therapeutically effective. Applicant alone has originally discovered and disclosed for the public benefit the efficacy of the various disclosed substances all for treating amyloidoses, and amyloid and alpha-synuclein fibrillogenesis, and alone is entitled under the law to claims of commensurate scope with this discovery and disclosure. It is after all the policy underlying the law, and the very constitutional provision for patents itself, that the public be bettered by so encouraging just this kind of discovery and disclosure with the issuance of patent grants.

Claims 1 - 21 stand rejected under 35 USC §112 as allegedly indefinite; Applicant respectfully traverses these rejections as well. The Examiner alleges in particular that the word 'standardized' in the claims is not defined in the claim, and further states that each claim must be self-contained. Applicant respectfully submits that it is well established that a claim is no less self-contained for using a term as defined elsewhere in the specification. As the Examiner notes, the word 'standardized' is defined in the specification as "50% polyphenols" (Examiner's note, lines 2-3 of first section 112 rejection), and this is well born out in the specification in general. Claims 1 and 11 are therefore not rendered indefinite by the occurrence of this term. It is believed they are otherwise in condition for allowance, and reconsideration is requested.

The Examiner further states that the occurrence of various terms such as, 'associated', 'including', and 'related,' constitute a broad range / narrow range type of problem. The term 'including' occurred only claims 2 and 8. Claims 8-9 have been canceled and are therefore moot; 'including' has been deleted from claim 2 for the sake of clarity only. The term 'related' occurs only in claim 18 where it is part of an construction well known to those skilled in the art and therefore not in any way confusing or indefinite to such skilled persons. In particular it is well known that certain "brain or cognitive disorders" are "age-related"; it is submitted therefore that this is not an indefinite construction or use of the term 'related.' A hyphen has been added for the sake of enhanced clarity. Similarly, the term 'associated' occurs in claims 18 and 19 as part of 'age-associated' or 'brain-associated' which are both likewise well known constructions in the context of discuss various pathologies of the brain. Hyphens have also been added for the sake of enhanced clarity. The terms 'associated' and 'type' occur differently, but no less permissibly, in claim 2; in claim 2, associated is used in a well known way to list the various amyloidoses in the manner conventional in the literature when discussing such a list; certain amyloidoses are simply better known and more succinctly listed by referring to them as the "___[amyloidosis] associated with" and then following with a listing of diseases with which that particular amyloidosis is well known to be associated. Similarly, the term 'type' is part of a well known naming convention for naming the amyloidosis that is a particular form of diabetes called "type II diabetes." Like the other constructions discussed above, these constructions are well known to those skilled in the art and therefore not in any way confusing or indefinite to such skilled persons.

The term 'such as' has now been deleted form claim 2 for clarity and replaced with 'and', and the term 'various forms of' which occurred only in claim 2 has been deleted. No other claims from among 1-21 are discussed in particular, and those not discussed are therefore believed to be

allowable under section 112 without further discussion; all other claims remaining are believed to be allowable in view of the foregoing discussion and reconsideration is requested.

Claims 1-4 and 10-11 stand rejected under 35 USC §102 as allegedly anticipated by Castillo WO 98/51302; Applicant respectfully traverses these rejections. Independent claims 1, 4 and 11 all require administering a green tea substance in general or a catechin or the like compound in particular; Castillo does not make any mention of green tea at all and no particular mention of catechins, bioflavanoids, flavanols, flavandiols, flavanoids, or tannins. Castillo thus does not anticipate claims 1, 4 or 11. Claim 10 depends from claim 1 and properly construed contains all the limitation of claim 1, and is therefore not anticipated either. These claims are all believed to be allowable over Castillo, and reconsideration is requested.

Claims 1-4 stand rejected under 35 USC §102 as allegedly anticipated by JP 10245342 (Mitsui Norin); Applicant respectfully traverses these rejections. Independent claims 1 and 4 all require administering a green tea substance or a catechin or the like compound to a subject to treat an amyloidosis (claim 1) or to treat amyloid fibril formation (claim 4); Mitsui Norin (cited by the Examiner only as an abstract, and now fully retrieved and also translated at Applicant's direction) does not make any mention of amyloidosis treatment or fibril formation at all. Mitsui Norin teaches narrowly only that nerve cell toxicity supposedly caused by beta-amyloid protein may be reduced with tea polyphenols; the reference makes no suggestion about treatment of amyloidosis or reduction of amyloid fibril formation, or disruption/disassembly of pre-formed amyloid fibrils at all. Applicant on the other hand teaches and claims a method of use of disclosed substances to actually interfere with and prevent or reverse amyloid and alpha synuclein fibril and plaque formations. Claims 1 and 4 therefore do not read upon any teaching or suggestion by Mitsui Norin, since the reference discusses only nerve cell death. Mitsui Norin's teaching is thus also not inherent in claims 1 and 4 and does not anticipate claims 1 or 4. These claims are all believed to be allowable over Mitsui Norin, and reconsideration is requested. The Mitsui Norin JP

10245342 full reference and translation (copies attached for the convenience of the Examiner) are also noted as references CCC and DDD in a supplemental IDS to be filed shortly under separate cover.

Claims 1-9 and 11-12 stand rejected under 35 USC §102 as allegedly anticipated by Shin-ya; Applicant respectfully traverses these rejections. Independent claims 1, 4, 6 and 11 all require administering a green tea substance or a catechin or the like compound to a subject to treat an amyloidosis (claims 1 and 6) or to treat amyloid and alpha synuclein fibril formation (claims 4 and 11); Shin-ya (cited by the Examiner only as an abstract, and now fully retrieved and also translated at Applicant's direction) does not make any mention of amyloidosis treatment or fibril formation, or disruption/disassembly of pre-formed amyloid fibrils at all. Shin-ya teaches only that nerve cell death induced by active oxygen and supposedly mediated by beta-amyloid protein may be reduced with catechin; the reference makes no suggestion about treatment of amyloidosis or reduction of amyloid fibril formation at all. Applicant on the other hand teaches and claims a method of use of disclosed substances to actually interfere with and prevent or reverse amyloid and alpha synuclein fibril and plaque formations. The rejected claims therefore do not read upon any teaching or suggestion by Shin-ya, since the reference discusses only active oxygen induced nerve cell death. Shin-ya's teaching is thus also not inherent in the rejected claims and does not anticipate them. These claims are all believed to be allowable over Shin-ya and reconsideration is requested. The Shin-ya full reference and translation (copies attached for the convenience of the Examiner) are also noted respectively as reference EEE in a supplemental IDS to be filed shortly under separate cover and BBB in the IDS earlier filed 2/11/02.

Claims 1-9 and 11-21 stand rejected under 35 USC §102 as allegedly anticipated by Schultes; Applicant respectfully traverses these rejections. The rejected claims all require administering a green tea substance or a catechin or the like compound to a subject to treat an amyloidosis (claims 1 and 6) or to treat amyloid fibril formation (claims 4 and 11) or to deal with

various brain, mental or pancreatic conditions (claims 13-21). Schultes does not make any mention whatever of green tea, Camellia sinensis or catechin or amyloidosis treatment or fibril formation; Schultes deals narrowly only with certain naturally occurring cholinesterase inhibitors and the view that certain dementias like Alzheimer's might be susceptible to treatment with such inhibitors. The reference is concerned not at all with reduction of amyloidosis or amyloid fibril formation. Applicant teaches and claims a method of use of disclosed substances to actually interfere with and prevent or reverse fibril and plaque formations, which are the basis of amyloidoses. The rejected claims thus do not read upon any teaching or suggestion by Schultes and Schultes' teaching is thus not inherent in the rejected claims and does not anticipate them. These claims are all believed to be allowable over Schultes and reconsideration is requested.

Applicant believes that it has responded fully to all of the concerns expressed by the Examiner in the Office Action, and respectfully requests reexamination of all rejected claims and early favorable action on them as well. If the Examiner has any further concerns, Applicant requests a call to Applicant's attorney Patrick Dwyer at (206) 343-7074.

Respectfully submitted,

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Amended Claims
(Version with Markings to Show Changes Made)

1. A method of treatment, prevention, or management of an amyloidosis in a mammalian subject susceptible to, or afflicted by, the amyloidosis, the method comprising the step of administering to the subject a therapeutic amount of a substance selected from the group of substances consisting of green tea, green tea leaves, standardized green tea extract, catechins, bioflavanoids, flavanols, flavandiols, flavanoids, and tannins and well known derivatives of any of the foregoing substances ~~plant matter from a source of green tea, green tea leaves, standardized green tea extract, or green tea derivative~~.

112-1st
112-2nd.

2. The method of Claim 1, wherein the amyloidosis is selected from the group of amyloidoses consisting of Alzheimer's disease, type II diabetes, Down's syndrome, hereditary cerebral hemorrhage with amyloidosis of the Dutch type, the amyloidosis associated with chronic inflammation, ~~various forms of~~ malignancy and familial Mediterranean fever, the amyloidosis associated with multiple myeloma and other B-cell dyscrasias, the amyloidosis associated with type II diabetes, the amyloidosis associated with the prion diseases, ~~including~~ Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, kuru and animal scrapie, the amyloidosis associated with long-term hemodialysis and carpal tunnel syndrome, the amyloidosis associated with senile cardiac amyloid and familial amyloidotic polyneuropathy, and the amyloidosis associated with endocrine tumors and~~such as~~ medullary carcinoma of the thyroid.

4. A method for the treatment, inhibition, prevention or management of amyloid fibril formation, deposition, accumulation, aggregation and/or persistence in Alzheimer's disease, type II diabetes and other amyloidoses in a mammalian subject, the method comprising the step of administering to the subject a therapeutic amount of a substance selected from the group of substances consisting of green tea, green tea leaves, standardized green tea extract, catechins,

112-1st 112-2nd

bioflavanoids, flavanols, flavandiols, flavanoids, and tannins and well known derivatives of any of the foregoing substances~~green tea, green tea leaves, standardized green tea extract, green tea derivative, catechins, bioflavanoids, flavanols, flavandiols, flavanoids, tannins or derivatives thereof~~.

11. A method for the treatment, inhibition, prevention or management of α-synuclein fibril formation, deposition, accumulation, aggregation and/or persistence in Parkinson's disease or Lewy body disease in a mammalian subject, the method comprising the step of administering to the subject a therapeutic amount of a substance selected from the group of substances consisting of green tea, green tea leaves, standardized green tea extract, ~~green tea derivative,~~ catechins, bioflavanoids, flavanols, flavandiols, flavanoids, and tannins and~~or~~ well known derivatives ~~thereof~~ any of the foregoing substances.

112-1st 112-2nd

18. A method for reducing in a patient one or more of the mental or cognitive effects selected from the group of mental or cognitive effects consisting of, age-associated cognitive or memory decline, mental decline, and likelihood of age-related brain or cognitive disorders, the method comprising the step of administering to the patient a therapeutically effective amount of plant matter from a plant of the genus Camellia, species sinensis.

19. A method for reducing, disrupting, dissolving, inhibiting, eliminating or preventing in a patient one or more conditions involving the brain selected from the group of conditions involving the brain consisting of amyloid fibril deposits, amyloid protein deposits, brain-associated amyloid fibril deposits, brain-associated amyloid protein deposits, amyloid fibril formation and growth, age-associated amyloid fibril formation and growth, brain-associated amyloid fibril formation and growth, the method comprising the step of administering to the patient a therapeutically effective amount of plant matter from a plant of the genus Camellia, species sinensis.